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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,137	08/29/2001	Christopher M. Angelucci	8932-538	6603

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PENNIE AND EDMONDS
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NEW YORK, NY 100362711

EXAMINER

ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 11/21/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,137

Applicant(s)

ANGELUCCI ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 22, 26 and 32-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-21, 23-25 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-4, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Invention I, i.e. claims 1-43, and Species I, i.e. Figure 1A-1C, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Species I, II, and V are directed to an implant for use in the spinal column, that the classification for them will be the same and the field of search will be the same. Also applicants refers to MPEP 808.02. This is not found persuasive because "species are always the specifically different embodiments" (see MPEP 806.04(e)) and the different embodiments presented in the drawings are independent from each other. The Species or different embodiments are patentable different from each other, as stated in the election requirement (see paper no. 5). Furthermore, it is not necessary to show a separate status in the art or separate classification (see MPEP 808.01(a)). Moreover, 806.04(e) states that "Election of species should not be required if the species claimed are considered clearly unpatentable (obvious) over each other." and applicants have not traverse the election requirement on the ground that the species are not patentably distinct, thus confirming the examiner's position. Also, applicants have not submitted evidence or identified such evidence now of record showing the Species to be OBVIOUS variants or clearly admitting on the record that this is the case. With regard applicants referral to MPEP 808.02, it is noted that 808.02 is related to related inventions which are shown to be distinct under the criteria of MPEP 806.05(c)-806.05(i), e.g. see restriction requirement of Inventions I-IV in paper no. 5. As stated above, for election requirement of Species, it is not necessary to show a separate status in the art or separate classification (see MPEP 808.01(a)).

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It is acknowledged that applicants believe claims 1-34 read on the elected Species I, i.e. Figures 1A-1C. It is noted that comparison of the claims with Figures 1A-1C and the specification shows, however, that the Species I, i.e. Figures 1A-1C, does not have first and second bone flaps which connects to and extend from the body portion and each flap having a hole as required in claims 9-12, or at least one of the bone engaging portions having surface projections as required in claims 22, 26, and 32-34. There is no generic claim.

Claims 9-12, 22, 26, and 32-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 13-21, 23-25, and 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, "the spinal column" lacks a prior antecedent.

In claim 13, lines 1 and 2, "the intermedullary canal of the donor bone" lacks a prior antecedent.

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In claim 14, lines 2 and 3, "the intermedullary canal of the donor bone" lacks a prior antecedent.

In claim 23, line 1, "the spinal column" lacks a prior antecedent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 6, 7, 13, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul et al. (Reference "WO 99/38461" cited on IDS).

Paul et al. disclose an implant comprising a body portion, e.g. 10, having a length, a width and a depth. The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface, e.g. 26 (see Figure 7), and an inner surface defining a substantially hollow portion, e.g. 11. The body portion further has first and second ends, e.g. 14 and 16, which communicate with the hollow portion 11. The first and second ends comprise bone engaging portions comprising rough surfaces that include peaks, i.e. teeth 12, and valleys, i.e. space between teeth. The valleys are considered cutouts. The rough

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surfaces, i.e. peaks and valleys, are adapted to engage and retain one of the cut bone segments.

The perimeter of the outer surface of the implant is a geometric shape, e.g. oval, square, etc. (see Figures 7 and 9). One embodiment of the implant is oval or elliptical (see Figure 7). The implant is tubular shape, e.g. Figure 8. The implant is formed from bone allograft material.

Claims 1, 2, 5, 6, and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by McKay (Reference US Patent "6,039,762" cited on IDS).

McKay discloses an implant comprising a body portion, e.g. 15, having a length, a width and a depth. The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface and an inner surface defining a substantially hollow portion 18 (see Figure 2). The body portion further has first and second ends that communicate with the hollow portion 18. The first and second ends comprise bone engaging portions having cutouts (see Figures 2-4). The perimeter of the outer surface of the implant is a geometric shape, e.g. circle (see Figure 2). The implant is tubular shape. The cutout includes at least two angled faces. The implant further includes at least one hole, e.g. 16, in communication with the outer surface and the inner surface. The implant is fabricate from biocompatible metal or any other material stronger than the porous biocompatible material 11 (see col. 5, lines 46-58).

Claims 1, 2, and 16-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Yonenobu et al. (Reference "JPO2000175943" cited on IDS).

Yonenobu et al. disclose an implant comprising a body portion 10 having a length, a width and a depth (see Figure 1). The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface and an inner surface defining a substantially hollow portion 17. The body portion further has first and second ends

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that communicate with the hollow portion 18 (see Figure 1B). The first and second ends comprise bone engaging portions 13, 14 having cutouts. The perimeter of the outer surface of the implant is a geometric shape. The cutout includes at least two angled faces and they have an arcuate shape. The implant further includes at least one hole or opening in communication with the outer surface and the inner surface. The implant is fabricate from biocompatible metal or another such material (see paragraph 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 8, 20, 21, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (Reference "WO 99/38461" cited on IDS).

Paul et al. disclose the claimed invention except for the length ranging from about 11.5 to about 15.5 mm, the width ranging from about 8.0 to about 9.0 mm, and the depth ranging from about 5.5 to about 6.5 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Paul et al. having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claim 5, i.e. the

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geometric shape being a circle, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of Paul et al. having a geometric shape like a circle, since is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of adapting the implant to the implanting site. In re Dailey and Eilers, 149 USPQ 47 (1966). With regard to claims 8, 20, 21, and 28-31, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Paul et al, from demineralized cortical bone, or biocompatible metal, or biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 3, 4, 7, 8, 13, 14, 16, 17, 21, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (Reference US Patent "6,039,762" cited on IDS).

Paul et al. disclose the claimed invention except for the geometric shape being an ellipse (claim 3), or the cutouts being arcuate shape (claims 16 and 17). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of McKay having a geometric shape like an ellipse or the cutouts having an arcuate shape, since is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious. In re Dailey and Eilers, 149 USPQ 47 (1966). With regard to claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of McKay having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from

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about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claims 7, 8, 13, 14, 21, and 28-31, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of McKay from bone allograft material, or demineralized cortical bone, or biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 3-8, 13, 14, 21, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonenobu (Reference "JPO2000175943" cited on IDS).

Yonenobu et al. disclose the claimed invention except for the geometric shape being an ellipse, or a circle, or the implant being tubular shape. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of Yonenobu et al. having a geometric shape like an ellipse or circle or the implant having a tubular shape, since is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of adapting the implant to the implant site. In re Dailey and Eilers, 149 USPQ 47 (1966). With regard to claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Yonenobu et al. having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller,

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105 USPQ 233. With regard to claims 7, 8, 13, 14, 21, and 28-31, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Yonenobu et al. from bone allograft material, or demineralized cortical bone, or biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Allowable Subject Matter

Claim 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 23-25 and 27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Conclusion

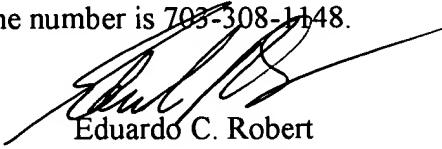
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.